UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,577	03/12/2001	Herbert Schlachter	0147-0220P	5756

2292 7590 03/10/2005

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No.	Applicant(s)	
	09/743,577	SCHLACHTER, HERBERT	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13,17-19 and 22-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-13,17-19 and 22-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt for Request for Continued Examination and Amendments/Remarks received on November 8, 2004 is acknowledged. Claims **2-13, 17-19 and 22-40** are pending in this application. Claims 1, 14-16, and 20-21 stand cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, hematomas, hemorrhoids, does not reasonably provide enablement for treating herpes, rheumatism, arthrosis, and skin cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in the view of the Wands factors (MPEP 2164.01 (a)). These include the nature of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, and state of the prior art. All of the Wands factors have been considered with the regard to the instant claims, with the most relevant discussed below.

Nature of the Invention: Rejected claim 40 is drawn to a method of treating skin irritations, sun burn, cellulites, wrinkles, acne, neurodermatitis, ozone damage, burns, caustic burns, thickening, edemas, herpes, hematomas, hemorrhoids, rheumatism, arthrosis, and skin

cancer with a topical composition containing 1) an alkali or alkaline earth metal salts or other minerals, 2) at least one amino acid, 3) zinc oxide or an inorganic peroxide, 4) and a secondary plant substance.

Breath of the claims: The complex nature of the claims is greatly exacerbated by the breath of the claims. The invention encompasses treating a *divergent* skin disorders ranging from minor skin irritations to skin cancer, which are caused by unrelated factors, with one topical composition.

Guidance of the Specification: The guidance by the specification discloses that the individual "recipe" of the composition provides for a certain treatment. Thus, depending on the active agents added, the desired disorder will be treated. However, rejected claim 40 recites a generic composition of four broad elements to treat all the divergent skin diseases listed, whereas the specification states that the treatment depends on the recipe. Thus, the specification is limited, if not lacking, in guidance on the "recipe" that actually treats the skin disorder of choice. For instance, the specification does not provide one reasonable guidance on how to treat skin cancer, herpes, arthrosis, or rheumatism.

Working Examples: All of the working examples provided by the specification are directed towards the improvement of wrinkles and microcirculation. The examples do not speak on the treatment of other divergent skin disorders such as skin cancer or herpes, with the generic composition.

The State of the Art: The prior art teaches various drugs to treat the divergent diseases listed in claim 40. For instance, the prior teaches the use of antivirals to treat herpes, however the instant invention claims to treat herpes without the requisite antiviral agents. Further, the art

teaches the use of anti-inflammatories to treat rheumatism and arthrosis (a degenerative disease of the joints), which are both characterized by pain and inflammation of the joints. Lastly, the prior art teaches the use of cytoxic drugs, i.e. neoplastic agents, anticancer agents, etc., to treat skin cancer. Thus, it can be seen that the composition that is directed to treating these disorders does not have the requisite drug to treat the skin disorder.

Undue Experimentation: The instant invention requires undue experimentation to find the appropriate "recipe" to treat the appropriate disease. Firstly, there is a multitude of possible combinations of the optional ingredients in the specification. Thus, a skilled artisan would first need to ascertain the appropriate combination of components in the exahasitive list in the specification, then a skilled artisan would need to test the each possible combination, and the skin disease and ascertain which skin disorder, the combination treats. Thus, the instant invention requires undue experimentation for a skilled artisan to practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-13, 17-19 and 22-40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims recite "phytin acid" as the secondary plant substance in a Markush group, which is indefinite. It is unclear if the applicant intends to claim phytic acid.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 7-9, 11, 17, 18, 19, 30-35, and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Abad (5,538,740).

Abad discloses a therapeutic and cosmetic composition for dermatitis, rashes, burns, wrinkles, and regeneration of the skin. The composition contains gastropod secretions, which contain a mixture of amino acids and atoxic substances, as the active ingredient. See abstract. Specifically, example III discloses the composition of the secretion, which contains the instant amino acids recited in claim 11. Example IV discloses the excipient that is commonly utilized with the secretion (active ingredient). The excipient contains cetyl alcohol, zinc peroxide, polyethylene glycol (humectant), and calcium carbonate. Lastly, example XIV discloses a body deodorant that contains the active ingredient, the excipient of example IV, menthol (the secondary plant substance), chlorophyll, and boric acid (antimicrobial).

Note that applicant amended the claims 11/8/05 to remove the phrase "in pure form", thus Abad read on the instant rejected claims. The examiner suggests amending the claim to "at least one individual amino acid in pure form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Rejection of claims 2-9, 11, 13, 17-19, 22-35, and 38-40 under 35 U.S.C. 103(a) as being unpatentable over Hersh et al (5,667,791) is maintained.

Hersh et al teach a topical composition for skin damage containing 1) squalene, 2) 3) vegetable oil which inherently containing polyunsaturated fatty acids, 4) seaweed which inherently contains polyphenols, 4) green tea (epigallocatechin), 5)Vitamin B, 6) Vitamin C, 7) glycopeptide zinc, 8) Epidermal Growth Factor, 9) selenomethionine and other components. Hersh teaches that zinc enhances the invention and that zinc oxide may function by healing properties on wounds. The zinc salt is contained in the amount of 0.001 to 8%. See column 9, lines 30-45.

Hersh et al do not exemplify zinc oxide in the composition.

Although Hersh does not exemplify zinc oxide in the composition, it is deemed obvious to one of ordinary skill in the art to look at the guidance provided by Hersh et al and incorporate zinc oxide in the composition. One would have been motivated to do so since Hersh teaches the importance of the inclusion of zinc salts and that zinc oxide has healing properties. Therefore, one would have been motivated to add zinc oxide into Hersh's therapeutic composition for skin damage for its healing skin wounds.

Response to Arguments

Applicant's arguments filed 11/8/05 have been fully considered but they are not persuasive.

Applicant argues that Hersh does not teach "at least one individual amino acid" since Hersh discloses selenomethione and this is not considered an amino acid. Applicant argues that a person of ordinary skill would not consider selenomethione as an individual amino acid. Applicant argues that selenomethione is an organometallic compound wherein the sulfur atom in methionine is replaced by a selenium atom and thus is different from an organic amino acid. Moreover, applicant the inventor an "expert in the field" would know that amino acid does not include selenomethione or derivatives. Applicant submits that journal articles, books, and sophisticated technology readily notes the difference.

Firstly, the examiner is not stating that an amino acid derivative and amino acid are equivalent, it is noted that they are different. Furthermore, although an "expert" in the field would readily know that an amino acid derivative might not read on an amino acid, the examiner points out that claims are given its broadest reasonable interpretation to one of *ordinary skill in the art*. The claims merely recite "an individual amino acid" and the scope of the claims include amino acid derivatives since the derivatives are in fact amino acids with substitutions. Secondly, the examiner notes the art of interest cited, however she maintains her position since there is evidence supporting both sides, i.e. the applicant's assertions and the examiner's. Although the art of interest states that selenomethione is amino acid containing selenium atom, the examiner points out that the term amino acid is utilized to categorize the compound.

Moreover, with regard to applicant's differentiation between amino acids and amino acid derivatives, page 7 of the instant specification is pointed to:

> The preparation of the present invention can contain all known amino acids and amino acid derivatives. Preferred amino acids and amino acid derivatives are alanine, phenylalanine, cysteine, cystinç, proline, tyrosine, serine, histidine, glycin, leucine, isoleucine, valine, tryptophan, arginine, lysin, asparagine and glutamine. Particularly cystine, cysteine, proline, serine, histidine, lycine, leucine, isoleucine, valine, tyrosine, arginine, lysin, asparagine and glutamine are used. Cystine, histidine, glycin, leucine, valine, arginine, lysin and glutamine are especially preferred. The D-form, DL-form and L-form of the amino acids can be used, whereby the L-form is preferred. Examples for amino acid derivatives are N-acetylated forms, e.g. N-acetyl-L-glutamine, N-acetyl-L-tyrosine and N-acetyl-DL,- tryptophan. The amino acids and amino acid derivatives can be used solely or in the form of mixtures. The amount of amino acids and amino acid derivatives in the preparation of the present invention is preferably 0. 1 to 40 percent by weight, more preferably 0.2 to 30 percent weight, most preferably 0.2 to 15 percent by weight, based on the sum of all components in the preparation. The amino acids and their derivatives are preferably added in a pure form.

The applicant demonstrates the equivalency of amino acid, their derivatives, and mixtures of the amino by stating that either one may be used. Thus, the criticality of an amino acid versus its derivative is not seen.

Accordingly the rejection is maintained.

Rejection of claims 2, 6-7, 9-12,17-19, 28-31, and 34-40 under 35 U.S.C. 103(a) as being unpatentable over Hillebrand (5,296,500) is maintained.

Hillebrand teaches a method of regulating wrinkles with a topical composition containing water, glycerin (humectant), tocopherol (vitamin E), N-acetyl-L-cysteine (amino acid derivative), zinc oxide, and sodium hydroxide (component a). see example 4 in particular. The

composition may contain conventional additives such as soybean saponins and polysaccharides (secondary plant substance). See column 7, line 64. Zinc salts such as zinc oxide, zinc peroxide, etc. are taught in the amount of 0.001-10%. See column 4, in its entirety. Zinc oxide is taught as a sunscreen agent and is generally included in the amount of 1-20%. See column 8, line 44 to column 9, line 50. The composition is rendered odorless by utilizing zinc salts incorporated in the amount of 0.001-10%. See column 4.

Hillebrand does not exemplify a plant substance.

Although, Hillebrand does not exemplify plant substance, it is deemed obvious to one of ordinary skill in art to look to the guidance provided by Hillebrand and incorporate the instant plant substance, i.e. soybean saponins. One would have been motivated to do so since Hillebrand teaches the conventional additives such as saponins in the cosmetic art and in the composition. Therefore, it is obvious to a skilled artisan to add conventional additives known and routinely used. Lastly, , it is within the skill of an artisan to manipulate the concentrations of the prior art.

With regard to claim 12, one would have been motivated to use zinc peroxide instead of zinc oxide since Hillebrand teaches the suitability of a variety of zinc salts including zinc peroxide. Therefore, a skilled artisan would have been motivated to use zinc peroxide instead of zinc oxide in example 4, with the expectation of similar results.

Response to Arguments

Applicant's arguments filed 11/8/05 have been fully considered but they are not persuasive.

Applicant argues that Hillebrand does not teach "at least one individual amino acid" since Hersh discloses N-acetyl-L-cysteine and this is not considered an amino acid. Applicant argues

that a person of ordinary skill would not consider N-acetyl-L-cysteine as an individual amino acid.

The arguments pertaining to a amino acid versus a derivative have been addressed above.

Applicant argues that there is not motivation to combine the soybean saponin since it is in a laundry list. Further, applicant argues that there is no motivation to utilize an amino acid, zinc oxide/peroxide, and a plant substance (SPS).

In regards to the argument that SPS is not exemplified, the examiner points out that the rejection is made under obviousness rejection and does not have to exemplify the instant invention. It is again pointed out that disclosed examples do not constitute a teaching away from the broader disclosure. See In re Susi. Further, a reference may be relied upon for all that it reasonably suggest to one of ordinary skill in the art, including nonpreferred embodiments. The art has to suggest the instant invention, which it does. On column 7, lines 60-65, Hillebrand clearly teaches the incorporation of conventional additives such as EGF, essential oils, and soybean saponins. It is further pointed out that Hillebrand teaches nine **conventional** additives, this is not considered a "laundry list" as argued by the applicant. Further, the use of a conventional additive is not unexpected.

With regard to the argument that the reference does not teach the pharmaceutically effective amount of the SPS, the examiner points out that the applicant is relying on a feature that is not claimed.

Lastly, with regard to the argument that the zinc is utilized for another reason, the fact that applicant has recognized another advantage which would flow naturally from following the

suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Accordingly, the rejection is maintained.

Claims 2-4, 6-7, 9-11, 13, 17-19, 22-25, 28-31, and 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (5,378,461).

Neigut teaches a composition for the topical treatment of skin damage. Example 5 contains squalene (carrier), propylene glycol (emollient), Vitamin A, D< E, CoQ10, gamma linoleic acid (unsaturated fatty acid), lecithin, 500mg L cysteine, 500mg L methionine, 50mg sodium selenite (alkali metal salt), 2500mg dimethyl glycine, 250mg zinc oxide, and 35-125g corn starch. Neigut teaches the use of colloidal oatmeal (dietary fiber) or other starches in the place or in combination with the corn starch. Further, beta carotene is taught for its antioxidant properties.

Neigut does not exemplify oatmeal in the composition.

Although, Neigut does not exemplify plant substance, it is deemed obvious to one of ordinary skill in art to look to the guidance provided by Neigut and incorporate oatmeal into the composition. One would have been motivated to do so since Neigut teaches the us of starch or oatmeal as the binder in the composition. Therefore, a skilled artisan would have expected similar results by utilizing oatmeal instead of the exemplified corn starch. Further, Neigut teaches the use of beat-carotene ,which is a carotinoid pigment, for its antioxidant properties. Thus, a skilled artisan would have been motivated to further add beta-carotene in the composition for its antioxidant properties.

Claims 5 and 26-27are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (5,378,461) in view of Touzan et al (5,468,496).

The teachings of Neigut as been set forth above. Neigut teaches the use of a surfactant to prevent the separation of the oil and water components. See column 9, lines 16-20.

Neigut does not specify the use of tego-betaine.

Touzan et al teach a two-phase cosmetic or dermatological composition. The reference teaches the use of surfactants to stabilize the composition such as amphoteric surfactants that are present in the aqueous phase. Tego-betaine is taught as a preferred surfactant in the amount of 0.5-1%. See column 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Neigut and Touzan et al and utilize tego-betaine in the composition of Neigut. One would have been motivated to do so since Touzan teaches tego-betaine as a amphoteric surfactant to stabilize a emulsions. Further, one would have expected success since Neigut teaches the use of a surfactant. Therefore, a skilled artisan would have been motivated to utilize a surfactant to prevent separation of the phases in Neigut's composition.

Conclusion

None of the claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SSG

MICHAEL HARTLEY
PRIMARY EXAMINER